



UNITED STATES PATENT AND TRADEMARK OFFICE

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United States Patent and Trademark Office  
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Leslie Morioka  
Patent Department, White & Case  
1155 Avenue of the Americas  
New York, NY 10036-2787

In Re: Patent Term Extension  
Application for  
U.S. Patent No. 4,738,974

**MAILED**

**MAR 31 2005**

Dear Ms. Morioka:

**REEXAM UNIT**

An order granting an interim extension under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,738,974 for a period of one year. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website:  
<http://www.fda.gov/opacom/morechoices/fdaforms/default.html>  
(<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf>).

Telephone inquiries regarding this communication should be directed to the undersigned by telephone at (571)272-7744, or at [Karin.Ferriter@uspto.gov](mailto:Karin.Ferriter@uspto.gov) by e-mail.

*Jerry J. Dey for*  
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Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy

cc: Office of Regulatory Policy  
HFD - 13  
5600 Fishers Lane  
Rockville, MD 20857

Attention: Claudia Grillo

RE: NEXIUM™ (esomeprazole)  
FDA Docket No.: docket no

UNITED STATES PATENT AND TRADEMARK OFFICE

In re Aktiebolaget Hassle  
Request for Patent Term Extension  
U.S. Patent No. 4,738,974

: ORDER GRANTING  
: INTERIM EXTENSION

Aktiebolaget Hässle, the owner of record in the United States Patent and Trademark Office (USPTO) of U.S. Patent No. 4,738,974, filed an application for patent term extension under 35 U.S.C. § 156 on April 19, 2001. The original term of the patent is due to expire on April 19, 2005. The patent claims the active ingredient esomeprazole in the human drug product "NEXIUM®," and a method of use of said product. "NEXIUM®" (esomeprazole) was approved by the Food and Drug Administration for commercial marketing or use on February 20, 2001. An extension of 865 days is requested.

The initial review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. A final determination of the length of the extension of the patent term and issuance of a patent term extension certificate cannot be made until a final determination of the length of the regulatory review period is made by the Food and Drug Administration. Because the original term of the patent would expire before a certificate of patent term extension can be issued, an interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,738,974 is granted for a period of one year from the original expiration date of the patent, until April 19, 2006.

Date

March 29, 2005

Jon W. Dudas  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office

